

## INVESTIGATIONAL DRUGS POLICY & PROCEDURES

At

### The JESSE BROWN VA MEDICAL CENTER (JBVAMC)

1. **PURPOSE:** To establish a policy and procedures governing the use of investigational new drugs (IND) at the Jesse Brown VA Medical Center and to establish guidelines for the proper processing and dispensing of investigational drugs.

2. **POLICY:** Investigational new drugs for human use will be stored and dispensed through the VA Pharmacy at JBVAMC in accordance with all applicable federal laws and regulations and Veterans Administration policy MCM 151-2. The JBVAMC/NU/UIC Collaborative Institutional Review Board and the VA Research and Development (R&D) Committee will approve all protocols involving INDs. One-time emergency- use of an investigational drug follows the procedures described in the UIC OPRS policy, *Emergency Use of a Test Article*.

#### 3. DEFINITIONS:

a An investigational drug is a drug or biological drug that is used in a clinical investigation. The FDA considers the term "Investigational New Drug (IND)" synonymous with investigational drug (21 CFR 312.3). However, based on VHA Handbook 1200.05, an Investigational Drug may be an approved drug that is being studied for an unapproved or approved use in a controlled, randomized or blinded clinical trial.

b. Investigational New Drug (IND). An IND is used to refer to either an investigational new drug application or to a new drug that is used in clinical investigations. IND is synonymous with "Notice of Claimed Investigational Exemption for a New Drug."

#### 4. PROCEDURE:

##### a. Approval of investigational drugs

(1) Application for use of an IND, as part of IRB approved research study, must be made to the Collaborative IRB and R&D Committee using the appropriate IRB and R&D research application forms including VA Form 10-9012. A copy of the research protocol also will be furnished to the VA Pharmacy by the R&D office after the

R&D Committee approval. The VA Research Pharmacist is a member in the R&D Committee.

(2) Emergency and/or humanitarian use of an investigational new drug may be deemed exempt from review by the IRB for patients outside an approved research protocol when the patient is in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval. The criteria for emergency use and procedures to be followed are outlined in the UIC OPRS policy, *Emergency Use of a Test Article* .

### **b. Custody and Dispensing of Investigational Drugs**

- (1) Investigational drugs will be maintained in the pharmacy by the Investigational Pharmacist, with the exception of radioactive agents.
- (2) Drug accountability will be recorded on forms provided by study sponsor and/or the Investigational Drug Dispensing Record form. These forms will be maintained by the Investigational Pharmacist in a protocol file. A record of each drug stored and dispensed will include the following:
  - (a) Name of drug, dosage form; and strength;
  - (b) Source of the drug (manufacturer, sponsor, and strength);
  - (c) IRB/R&D approved protocol, IRB number, approval dates (IRB and R&D), date protocol received, initial/continuing review dates of approval, and all versions of IRB approved consents and the corresponding effective dates, and Investigational Brochure;
  - (d) Amount and date received from source (including inventory notes);
  - (e) Expiration date, if any, for each prescription;
  - (f) Lot or control number, expiration, or retest date for each prescription.

Pharmacy will contact the study sponsor for retest date if expiration date is not provided on the drug package or shipment records and will document in the dispensing record the name and contact information for the person supplying the information. If the sponsor is unable to provide the information pursuant to their policies, (i.e., blinding of study drugs or continuous stability testing), the Investigational Pharmacist will request a statement to be filed in the dispensing record from a representative of the sponsor, the manufacturer or the distributor that attests that the expiration or retest dates are monitored centrally and dispensing sites will be notified prior to the assignment or dispensing of any drugs that are approaching an expiration date; Date of authority to use; Serial number and date of prescription dispensed; Patient's name and hospital identification number for each prescription; Notation confirming pharmacist's acknowledgement of appropriate consent form with proper signatures for each prescription; Amount dispensed for each prescription and remaining balance; Name of authorized prescriber(s) and initials of dispensing pharmacist for each prescription.

- (3) Only physicians or dentists specifically authorized by the IRB on VA Form 10- 9012 (Investigational Drug Information Record) can

prescribe an investigational drug.

(4) The Investigational Pharmacist will be responsible for the custody of all drugs involved in Protocols, approved by the IRB and R&D, except this policy does not apply to drugs used within Research laboratories for non-human purposes.

(5) Investigational drugs will be kept separate from other pharmacy drug stocks, and dispensed only upon prescription of the provider specifically authorized to prescribe the drug. The prescription must be dated, signed, and bear the patient's name, actual quantities prescribed, and directions for use. Additionally, a copy of the patient's signed Informed Consent Form must be contained within the Investigational Pharmacist's records. Upon request, the Investigational Pharmacist will provide a complete accounting to the IRB for each protocol's Continuing Review or for audit purposes, including the names of all patients' who received study drug(s) and the date the patient signed the consent form.

(6) A special investigational drug label, in addition to information required by law on prescription labels, will include the following legend, "FOR INVESTIGATIONAL USE ONLY", and other auxiliary, caution or warning labels as indicated.

(7) Additionally, a file containing the approved protocol with amendments, the signed Investigational Drug Information Record(s) (VA Form 10-9012), the Investigator Brochure, and copies of all subjects' signed Informed Consent Forms (VA Form 10-1086) will be maintained for all active drug studies.

(8) The final entry in each study record will be the date of disposition of any remaining drug after the completion of the study. Records will be maintained for a minimum of seven (7) years for all investigational drugs. Contact with the study sponsor will be made to determine disposition" of unused study drug. Drugs authorized by the sponsor to be destroyed will be sent to a contracted vendor for destruction of drugs by methods which are in compliance with hazardous waste handling.

(9) Following receipt and review of informed consent documentation, the primary Investigational Pharmacist will dispense investigational drugs, when feasible. Other designated pharmacists who have completed training on investigational pharmacy policies and procedures may perform this function in the absence of the primary Investigational Pharmacist. Drugs that require special handling (example: chemotherapy) will be prepared by the Chemotherapy Pharmacist in the Pharmacy Service after all of the required documentation has been received by the Investigational Pharmacist and the necessary information relayed to the Chemotherapy Pharmacist.

c. Consent for Use: The investigator will fully inform the patient about the study or use of investigational drugs, including possible known adverse reactions. The investigator will secure consent from the patient (or his guardian) by signatures on VA Form 10-1086 (Agreement to

Participate in Research by/or Under the Direction of the Veterans Administration) and the "Information About" document. These signed forms will become a permanent part of the patient's record. The investigator or study coordinator will forward to the VA Pharmacy a copy of the signed consent form for each new patient. The pharmacy will not dispense an investigational drug until a copy of the sign consent form is received with authorized signature page.

d. The principal investigator will complete Investigational New Drug Information Record (VA Form 10-9012) at the time of IRB and R&D review process. The R&D office will provide a copy of VA form 10-9012 to the VA Pharmacy.

e. Summary/Termination of Protocol: All records will be made available to the investigators and other authorized personnel while taking into consideration patient privacy rights.

f. Disposition of remaining IND stock: Unused stock will be returned or disposed of in accordance with the clinical trial protocol, FDA guidelines, Federal/State laws, and VA policy.